

# Exhibit B

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA *et al.*  
*ex rel.* JULIE LONG,

Plaintiffs,

V.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No.  
16-12182-FDS

**PLAINTIFF’S SUPPLEMENTAL OBJECTIONS AND RESPONSES TO  
DEFENDANT’S INTERROGATORIES 6 TO 18**

Pursuant to Federal Rules of Civil Procedure 26 and 33 and Local Civil Rule 33.1, plaintiff relator Julie Long (“Plaintiff”) hereby objects and responds to defendant Janssen Biotech, Inc.’s (“Defendant”) Interrogatories 6 to 18 (hereinafter, the “Interrogatories”), as follows:

## PRELIMINARY STATEMENT

The information contained in the responses set forth below is based upon information and documents currently available to Plaintiff. Plaintiff's investigation and discovery in this matter is not complete. Additional investigation and discovery may provide further information and documents relevant to these responses, as could information and documents obtained from Defendant and/or third parties through additional discovery procedures. The following responses are based upon information known at the time and are given without prejudice to Plaintiff's right to supplement these responses prior to trial or to produce evidence based on subsequently discovered information. Plaintiff's responses are based upon, and therefore limited by, Plaintiff's

present knowledge and, consequently, Plaintiff reserves the right to revise, amend, or supplement these responses as appropriate.

Plaintiff's responses to all or any part of the Interrogatories should not be taken as an admission that: (1) Plaintiff accepts or admits the existence of any fact set forth in or assumed by the interrogatory; (2) Plaintiff has in her possession, custody, or control documents responsive to that interrogatory; or (3) documents responsive to that interrogatory exist. Plaintiff reserves the right to contest Defendant's characterization of any facts, circumstances, or legal obligations as inaccurate.

Plaintiff's responses to all or any part of any interrogatory are not intended to be, and shall not be, a waiver by Plaintiff of all or any part of her objection(s) to that interrogatory.

#### **GENERAL OBJECTIONS**

Plaintiff incorporates the following general objections into each of the specific responses set forth below. Plaintiff does not waive any of these general objections in her responses to the specific Interrogatories. Any specific objection made by Plaintiff in no respect limits or modifies these general objections. Plaintiff's objections and responses are made without waiving or intending to waive, but rather intending to preserve and preserving: (1) all objections to competency, relevance, materiality, privilege, and admissibility as evidence for any purpose in this proceeding; (2) the right to object to, on any ground, any demand for further responses to these or any other discovery requests; (3) the right to preserve, prior to providing and as a condition of providing, the confidentiality of any information that may be provided or the subject matter thereof; (4) the right at any time to revise, supplement, clarify, or amend the responses and objections to the Interrogatories, if further factual developments or analysis warrants a

modification, or if additional information is obtained or documents are located that are properly called for by the Interrogatories; and (5) all rights existing at the time of this response.

Plaintiff's specific objections to each interrogatory are in addition to the general limitations and objections set forth in this section. These limitations and objections form a part of the response to each interrogatory and are set forth here to avoid the duplication and repetition of restating them for each response. The absence of a reference to a general objection should not be construed as a waiver of the general objection as to the specific interrogatory.

1. Plaintiff objects to the Interrogatories to the extent that the definitions and instructions seek to impose obligations beyond those required by the Federal Rules of Civil Procedure, Local Civil Rules, or Orders of this Court, or require production of materials or information prohibited by law. Plaintiff will comply with the requirements set forth in the Federal Rules of Civil Procedure, Local Civil Rules, and Orders of this Court, but will not comply with any definition or instruction that seeks to impose a greater requirement. In addition, Plaintiff objects to the Interrogatories insofar as they violate the Court's limitation that each party may serve no more than 25 written interrogatories, including all discrete subparts.

2. Plaintiff objects to the Interrogatories to the extent that they seek information: (a) that is protected from discovery pursuant to the attorney-client privilege, attorney work product doctrine, common-interest privilege, joint prosecutorial privilege, or any other applicable privilege, protection, immunity, or limitation on discovery; (b) that was prepared in anticipation of litigation; or (c) that is otherwise protected from disclosure under the Federal Rules, relevant federal procedural rules, or relevant case law. No information covered by any privilege, protection, immunity, or limitation will be intentionally disclosed. In the event that any such information is disclosed by Plaintiff, such disclosure is inadvertent and does not constitute a

waiver of any privilege, protection, immunity, or limitation from disclosure. Plaintiff reserves the right to demand the return of any privileged or otherwise protected information inadvertently produced during discovery.

3. Plaintiff objects to the Interrogatories to the extent that they purport to require information or production of documents concerning any expert or other person or entity retained by Plaintiff's counsel to assist in the preparation of Plaintiff's case but who will not be designated by Plaintiff as an affiant or witness on the grounds that such disclosure violates the attorney work-product doctrine and is not required by the Federal Rules of Civil Procedure.

4. Plaintiff objects to the Interrogatories to the extent that they seek legal conclusions and/or ultimate factual determinations. Plaintiff objects to the Interrogatories to the extent that they seek to force Plaintiff to prematurely adopt or lock into a legal position.

5. Plaintiff objects to the Interrogatories to the extent that they seek information, documents, or other materials that are within the possession, custody, or control of Defendant, and/or its counsel, and/or that are publicly available, and, therefore, may be accessed by Defendant with less burden than Plaintiff can identify and provide the requested information. In particular, the Interrogatories purport to require Plaintiff to replicate information already provided by Plaintiff to Defendant through the pleadings and during the course of discovery in this action.

6. Plaintiff objects to the Interrogatories to the extent that they seek information not within the possession, custody, or control of Plaintiff, or that are available from a more convenient, more efficient, less burdensome, or less expensive source. Plaintiff's search and responses will be limited to information reasonably in her possession, custody or control.

7. Plaintiff objects to the Interrogatories to the extent that they are not proportional to the needs of the case.

8. Plaintiff objects to the Interrogatories to the extent that they seek information that is not relevant to the claims or defenses of any party to this action, nor reasonably calculated to lead to the discovery of admissible evidence under the Federal Rules or otherwise purport to impose any obligation on Plaintiff beyond that required or permitted by the Federal Rules or the Local Rules, or other rules or practices applicable to cases in this Court.

9. Plaintiff objects to the Interrogatories to the extent that they are overbroad or seek irrelevant information and are therefore unduly burdensome.

10. Plaintiff objects to the Interrogatories to the extent that they are vague or ambiguous and, as such, would require Plaintiffs to speculate as to the meaning of the interrogatory.

11. Plaintiff objects to the Interrogatories to the extent that they prematurely seek information that is required to be disclosed in a pre-trial order, such as the identity of testifying witnesses or exhibits to be used at trial.

12. Plaintiff objects to the Interrogatories to the extent that they seek information that is duplicative, cumulative, and/or redundant of Defendant's requests for the production of documents or other discovery sought or provided in this action.

13. Plaintiff objects to the Interrogatories to the extent that they are compound and contain multiple numbered and unnumbered subparts.

14. Plaintiff objects to the Interrogatories to the extent that Defendant asserts Plaintiff's responses thereto constitute an adoption or acceptance of terms or definitions that Defendant has employed, including to the extent that it seeks to define terms and/or characterize

the evidence or pleadings in this matter. In responding to the Interrogatories, Plaintiff does not adopt, embrace, or accept any term or definition employed by Defendant. To the extent that Plaintiff adopts any terms used by Defendant in the Interrogatories, such adoption is specifically limited to these responses and shall not be construed as an admission. These responses are made based upon Plaintiff's interpretation of words contained in the interrogatory, unless a specific definition or instruction has been agreed upon.

15. Plaintiff objects to the Interrogatories to the extent that they misstate, misdescribe, or misconstrue Plaintiff's claims or allegations.

16. In submitting these responses, Plaintiff expressly reserves the right to object on any ground whatsoever to the use as evidence or any other use of the information provided in this or any other proceeding.

17. Plaintiff objects to the extent the Defendant's Interrogatories are directed to counsel.

18. Plaintiff objects to the Interrogatories to the extent that they seek to impose additional and/or different discovery obligations than those discovery obligations imposed pursuant to any orders entered by the Court and/or any agreements between the Parties regarding the discovery of electronically stored information and/or confidential information.

19. Plaintiff objects to Defendant's definition of the Phase 1 Accounts to the extent that it fails to take into account that certain physician practices within this sample set did business under different names and/or merged with other physician practices during the relevant period. Plaintiff responds below on the understanding that the term Phase 1 Accounts includes the predecessor and successor entities of the physician practices within the sample set.

20. Plaintiff objects to the Interrogatories because Janssen did not comply with the Court's instruction that the parties should seek leave of court before serving additional discovery requests. *See* Sept. 9, 2022 Order (ECF 322) at 5 n.3.

21. Plaintiff's answers are not an admission or agreement that the request is proper or a waiver of an objection, should interrogatories be made for further similar information.

### **OBJECTIONS AND RESPONSES**

**INTERROGATORY 6: Identify each instance in which You provided in-office infusion support services to any Phase One Account, including (i) the date on which You provided the in-office infusion support service(s); (ii) the Phase One Account to which You provided the service(s); and (iii) the in-office infusion support service(s) provided.**

#### **RESPONSE TO INTERROGATORY 6:**

Plaintiff objects to this interrogatory on the ground that it seeks information that is in Defendant's possession, custody, or control and that Plaintiff has requested in discovery but Defendant has not yet fully produced or provided. Additionally, this interrogatory is premature because discovery is still in the early stages, and Plaintiff has not yet completed her pretrial investigation, discovery, and preparation of her case for trial. Plaintiff objects to this interrogatory to the extent that it seeks an answer that may be determined by examining, auditing, compiling, abstracting, or summarizing Defendant's business records (including electronically stored information), and the burden of deriving or ascertaining the answer will be substantially the same for Plaintiff (likely more burdensome) as it would be for Defendant. Plaintiff objects to this interrogatory to the extent Janssen seeks to have Plaintiff compile or summarize information contained in the documents that she produced in this action and the burden of deriving or ascertaining the answer will be substantially the same for Plaintiff as it



would be for Defendant. Plaintiff objects to this interrogatory to the extent that it seeks to test Plaintiff's memory concerning information that Defendant already possesses. Plaintiff also objects to this interrogatory as overbroad and unduly burdensome on the grounds that it requests identification of "each instance" in which Plaintiff provided the services and related presentations and programs identified in Plaintiff's response to Interrogatory 2 to the Phase 1 Accounts.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: *See* Plaintiff's response to Interrogatory 2. Plaintiff offered or provided, or was involved in the offering or provision of, each of the services identified in the response to Interrogatory 2. However, Janssen may have started offering and providing certain presentations or programs identified in the response to Interrogatory 2 after Plaintiff left the company, including In-Office Infusion Drug Procurement Models; Infusing Practice Tool Kit; Infusion Practice Management Series; Medicare Quality Payment Program: A Focus on MIPS; Patient Experience in the Infusion Suite; and Specialty Drug Market Dynamics: Implications for Infusions. All of the services identified in the response to Interrogatory 2 were offered and available to the Phase 1 Accounts. In accordance with Janssen's directives, certain services and related presentations and programs identified in the response to Interrogatory 2 were provided to all the Phase 1 Accounts (*e.g.*, Infusion Optimization Modeler; Managing Biologics in the Physician Office; and IBiz). In accordance with Janssen's directives, certain services and related presentations and programs identified in the response to Interrogatory 2 were provided to those Phase 1 Accounts that either requested the services or related presentations or programs or Plaintiff and/or Plaintiff's managers determined that the account required or would benefit from the services or related presentations or programs (*e.g.*, Practice Pearl programs; Infusion Therapy Services Provided in

Converted ASC Space). The documents and information produced by Defendant or Xcenda, LLC, referenced in Plaintiff's response to Interrogatory 2, as well as the letters from Defendant's counsel dated August 11, 2021 and October 7, 2022 (Exhibit A to the letter), and Defendant's response to Interrogatory 18, report many of the dates when Defendant caused Plaintiff to provide the illegal services and related presentations and programs referenced in Plaintiff's response to Interrogatory 2 to the Phase 1 Accounts. Other documents and information that Janssen has produced to Plaintiff and documents that Plaintiff has produced to Janssen evidence the offering or provision of services and related presentations and programs identified in the response to Interrogatory 2 to Phase 1 Accounts, including, but not limited to, Monthly Reports, Plaintiff's performance evaluations, Plaintiff's Manager Based Objectives reports, and call activity information from Janssen's customer relationship management databases. Additionally, under Janssen's practices and policies, many of the services and related presentations and programs that Plaintiff provided to the Phase 1 Accounts were not specifically tracked or recorded.

Plaintiff will supplement this response after substantial discovery has been completed so as to provide a compilation of many of the dates when she provided the services and related presentations and programs identified in the response to Interrogatory 2 to the Phase 1 Accounts.

**INTERROGATORY 7: Identify each Phase One Account to which You provided in-office infusion support services that you believe opened up an in-office infusion suite as a result of the services You provided.**

**RESPONSE TO INTERROGATORY 7:**

Plaintiff advised, educated, and/or assisted the following Phase 1 Accounts concerning starting, setting up, and opening the initial in-office infusion suite ("IOI") within its practice:

- (1) Digestive Disease Associates, Ltd. (a/k/a Berks Center for Digestive Health);
- (2) Emkey Arthritis & Osteoporosis Clinic, Inc.;
- (3) Lancaster Gastroenterology, Inc. (a/k/a U.S. Digestive Health; Regional Gastroenterology Associates of Lancaster, Ltd.); and
- (4) Regional Gastroenterology Associates of Lancaster, Ltd. (a/k/a U.S. Digestive Health; Lancaster Gastroenterology, Inc.).

Plaintiff believes that the in-office infusion support services that she provided influenced and were a substantial factor in the accounts opening their initial IOI. In addition, Plaintiff believes that an Xcenda Gastro Business Specialist also provided certain in-office infusion support services, on behalf of Janssen, that influenced and were a substantial factor in Regional Gastroenterology Associates of Lancaster opening its initial IOI. Additionally, Plaintiff believes that the opening of the initial IOI by these accounts was a result of the in-office infusion support services that she provided and, in the case of Regional Gastroenterology Associates of Lancaster, that the Gastro Business Specialist provided.

Plaintiff also advised, educated, and/or assisted the following Phase 1 Accounts with opening an IOI in a new office/location (the accounts had already been operating an IOI before expanding its infusion business and opening an IOI at a new office/location):

- (1) Arthritis & Osteoporosis Center, Inc.;
- (2) Cumberland Valley Rheumatology, P.C. (f/k/a Schlansky & Clawson);
- (3) Sanford, Roumm, and Acharya Rheumatology LLC (f/k/a Sanford and Roumm Rheumatology);
- (4) Capital Arthritis and Rheumatology Associates, LLC (f/k/a George Kunkel, MD).

Plaintiff believes that the in-office infusion support services that she provided influenced and were a substantial factor in the accounts' expansion of its infusion business and opening of the IOI in the new office/location. Additionally, Plaintiff believes that the accounts' expansion and

opening of the IOI in a new office/location was a result of the in-office infusion support services that she provided.

**INTERROGATORY 8: Identify and describe each communication You had, including with employees of Defendant, in which you discussed, or raised concerns about, the legality of in-office infusion support services, prior to February 19, 2016. In your response, include (i) the date of each communication and (ii) the name of the individual(s) with whom You communicated.**

**RESPONSE TO INTERROGATORY 8:**

Plaintiff objects to this interrogatory to the extent that it seeks information that is protected from discovery pursuant to the attorney-client privilege or attorney work product doctrine.

Subject to the foregoing objection and the general objections, Plaintiff responds as follows: Plaintiff does not recall having any communications before February 19, 2016, in which she “discussed, or raised concerns about, the legality” of the services and related presentations and programs identified in her response to Interrogatory 2 with anyone other than her attorneys, including undersigned counsel and John F. Ward. Plaintiff’s communications with her counsel are protected from discovery pursuant to the attorney-client privilege and attorney work product doctrine.

**INTERROGATORY 9: Identify when you first determined that Defendant's provision of in-office infusion support services was illegal, and explain what led you to hold that belief.**

**RESPONSE TO INTERROGATORY 9:**

Plaintiff objects to this interrogatory because the information it seeks is not relevant to any claim or defense asserted in this action. Plaintiff further objects to this interrogatory because it seeks information that is protected from discovery pursuant to the attorney-client privilege.

Subject to the foregoing objection and the general objections, and without waiving the attorney-client privilege, Plaintiff responds as follows: Plaintiff first became aware that the in-office infusion support services that Janssen provided violated the law in or around the second quarter of 2016 after she had retained counsel.

**INTERROGATORY 10: Identify all remuneration conferred on the Phase One Accounts by Defendant that You allege was a kickback.**

**RESPONSE TO INTERROGATORY 10:** Plaintiff objects to this interrogatory on the ground that this interrogatory seeks information that is in Defendant's possession, custody, or control and that Plaintiff has requested in discovery but Defendant has not yet fully produced or provided. Additionally, this interrogatory is premature because discovery is still in the early stages, and Plaintiff has not yet completed her pretrial investigation, discovery, or preparation of her case for trial.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: *See* Plaintiff's responses to Interrogatories 2 and 6. Plaintiff alleges that Defendant's offering and provision (directly or indirectly through agents and representatives including outside consultants) of each form of remuneration identified in Plaintiff's response to Interrogatory 2 to the Phase 1 Accounts violated the Anti-Kickback Statute. Plaintiff further

alleges that Defendant's offering and provision (directly or indirectly through agents and representatives including outside consultants) of the forms of remuneration identified in Plaintiff's response to Interrogatory 2 to the Phase 1 Accounts as a part of a package or bundle of services and support violated the Anti-Kickback Statute.

**INTERROGATORY 11: State the basis for Your contention that the remuneration identified in Your response to Interrogatory No. 10 was a kickback.**

**RESPONSE TO INTERROGATORY 11:**

To the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute violation, Plaintiff objects because it is misusing this interrogatory to improperly attempt to obtain a detailed narrative of Plaintiff's case or pretrial memorandum. Plaintiff objects on the ground that responding to this interrogatory would be unduly burdensome, and it is not proportional to Defendant's needs during the discovery stage. Defendant has failed to show why the information requested in this Interrogatory is appropriate or necessary at this early stage of the discovery process. Plaintiff also objects on the ground that the interrogatory is premature because discovery is ongoing and is only in the initial stages and Plaintiff has not yet completed her pretrial investigation, discovery, or preparation of her case for trial. Additionally, documents that support Plaintiff's claims are in the custody, possession, or control of Defendant and are still in the process of being produced and reviewed and numerous depositions still need to be taken.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: The Anti-Kickback Statute states that "whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, ... order, ... or

recommend purchasing ... or ordering any ... service, or item for which payment may be made in whole or in part under a Federal health care program” shall be guilty of a felony. 42 U.S.C. § 1320a-7b(b)(2). The Anti-Kickback Statute “makes it illegal to offer, pay, solicit or receive anything *of value* as an inducement to generate business payable by Medicare or Medicaid.” *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39 (D. Mass. 2011) (quoting Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372, 65375 (Dec. 19, 1994)); Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35958 (July 29, 1991) (“Congress’s intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever. The statute’s language makes clear that illegal payments are prohibited beyond merely ‘bribes,’ ‘kickbacks,’ and ‘rebates,’ which were the three terms used in the original 1972 statute.”); *United States v. Regeneron Pharm., Inc.*, Civ. No. 20-11217-FDS, 2020 WL 7130004, at \*10 (D. Mass. Dec. 4, 2020). Liability under the AKS requires an “intent to induce a referral or recommendation,” and “[a]n intent to induce referrals ... means an intent ‘to gain influence over the reason or judgment’ of the [prescribing] physicians.” *Regeneron*, 2020 WL 7130004, at \*8 (quoting *United States v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 268, 271 (D. Mass. 2016)). A person who offers or pays remuneration to a health care provider violates the Anti-Kickback Statute “so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals.” *Id.* (quoting *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000)).

The services and related presentations and programs identified in the responses to Interrogatories 2 and 10 constitute “remuneration” as that term is used in the Anti-Kickback Statute. Although the meaning of “remuneration” is broader than the term “kickback,” as is commonplace in cases alleging Anti-Kickback Statute violations, Plaintiff uses the terms

remuneration and kickbacks interchangeably. Each kind of service and related presentation and program offered and provided (directly or indirectly through agents and representatives including outside consultants) had significant value and the value of the package or bundle of services and related presentations and programs offered and provided was even greater. In addition, the services and related presentations and programs (individually and collectively) had broad and significant independent value beyond Defendant's drugs Remicade and Simponi ARIA because the services were equally applicable to other infusion drugs and related to the management and operation of the entire in-office infusion suite as well as the physician practice. Alleged facts that support the allegation that the services and related presentations and programs had significant value include, but are not limited to:

- (A) The content and subject matter of the services and related presentations and programs;
- (B) Many of the presentations and programs were unbranded;
- (C) The services and related presentations and programs were frequently customized or selected to address a particular IOI business need or issue;
- (D) The services and related presentations and programs were provided by a special team of individuals with expertise in IOI and practice management - Areas Business Specialists;
- (E) Many of the services and related presentations and programs were provided by outside consultants including a law firm;
- (F) Statements and feedback from the recipients;
- (G) Statements by Janssen's employees and agents;
- (H) The increased efficiencies and profitability that the physician practices received as a result of the services and related presentations and programs;
- (I) The reduction in financial risk and overhead costs that the physician practices received as a result of the services and related presentations and programs;
- (J) The reduction of the burdens on the physician practices' staff as a result of the services and related presentations and programs;



- (K) The market value of the services and related presentations and programs;
- (L) Janssen's assessments of the value;
- (M) The amounts Janssen paid to furnish the services and related presentations and programs;
- (N) The demand for the services and related presentations and programs from physicians and their staff;
- (O) The presentations and programs utilized in providing the services were considered proprietary and were not disseminated publicly;
- (P) Janssen considered the services and related presentations and programs to give it a competitive advantage; and
- (Q) Janssen assisted with implementing or monitored the physician practices' progress in implementing the IOI optimization and practice management strategies.

One of Janssen's objectives or purposes for offering and providing the services and related presentations and programs identified in the responses to Interrogatories 2 and 10 was to induce health care providers associated with the Phase 1 Accounts to prescribe and infuse Remicade and/or Simponi ARIA to patients, including Medicare beneficiaries. Additionally, Janssen knew that this conduct was unlawful, but it voluntarily engaged in the conduct intending to do something the law forbids or disregard the law. Janssen's internal compliance policies, materials from the company's compliance training sessions, and its decisions to not seek advisory opinions from the U.S. Department of Health and Human Services Office of Inspector General support this allegation. The following alleged facts, among others, support the allegation that one of Janssen's objectives or purposes for offering and providing the services and related presentations and programs to the physician practices was to induce health care providers associated with the practices to prescribe and infuse Remicade and/or Simponi ARIA to patients, including Medicare beneficiaries:

- (A) The content and subject matter of the services and related presentations and programs;

- (B) Janssen's business plans;
- (C) Statements by Janssen's employees and agents;
- (D) Janssen's offer and provision of the services and related presentations and programs to only certain, not all, physician practice accounts/customers;
- (E) The volume of services and related presentations and programs offered and provided to accounts was based on an account's sales volume or potential sales volume;
- (F) Part of Area Business Specialists' compensation was based on the growth in sales of Remicade and Simponi ARIA within their accounts and on the number of IOIs opened and expanded;
- (G) Janssen closely monitored the impact of the services and related presentations and programs on utilization of Remicade and Simponi ARIA;
- (H) Janssen's return on investment analyses;
- (I) Janssen's requests for prescription and IOI expansion commitments;
- (J) Janssen's and its agents' descriptions of the purpose of the services and related programs and presentations;
- (K) Janssen considered the services and related presentations and programs to provide it a competitive advantage; and
- (L) Services and related presentations and programs were provided to blunt utilization of competing drugs.

Additionally, in performing the responsibilities of an Area Business Specialist, Plaintiff had direct knowledge of the services' and related presentations' and programs' value and Janssen's purpose in providing the services and related presentations and programs. Lou Zambelli and Mike Wolfe provided deposition testimony that support the allegations that the services and related presentations and programs were valuable and that one of Janssen's purposes or objectives in providing the services and related presentations and programs was to induce health care providers associated with the physician practices that received the services and related presentations and programs to prescribe and infuse Remicade and Simponi ARIA to patients,

including Medicare beneficiaries. Documents Plaintiff produced to Janssen in this action support the allegations that the services and related presentations and programs were valuable and that one of Janssen's purposes in providing the services and related presentations and programs was to induce sales. Documents that Janssen has produced to date support the allegations that the services and related presentations and programs were valuable, that one of Janssen's purposes in providing the services and related presentations and programs was to induce sales, and that the company was aware that it was acting unlawfully in providing the services and related presentations and programs to induce health care providers associated with the Phase 1 Accounts to prescribe and infuse Remicade and/or Simponi ARIA to patients, including Medicare beneficiaries. In addition, Plaintiff directs Janssen to Plaintiff's Second Amended Complaint, Plaintiff's briefing in opposition to Janssen's motion to dismiss the Second Amended Complaint, and Plaintiff's initial disclosures. Plaintiff will update her initial disclosures once Janssen has provided all the witness information that the Court ordered it to provide in the March 9, 2023 Memorandum and Order.

Plaintiff will supplement this response and list the evidentiary support for her Anti-Kickback Statute violation claims after substantial discovery has been completed.

**INTERROGATORY 12: Identify all False Claims that you allege Defendant caused the Phase One Accounts to submit to Medicare for the reimbursement of Remicade and Simponi ARIA.**

**RESPONSE TO INTERROGATORY 12:**

Pursuant to Federal Rule of Civil Procedure 26(a)(1)(A)(iii), Plaintiff's initial disclosures explained that damages will be subject to additional discovery and to expert opinion, and will be disclosed in accordance with the deadlines established by the Court. Plaintiff will rely upon

information and documents in the possession custody and control of the U.S. Department of Health & Human Services, some of which has been requested in accordance with the Court's phased discovery approach.

Plaintiff objects to this interrogatory to the extent that it seeks an answer that may be determined by examining, auditing, compiling, abstracting, or summarizing the Medicare claims data produced in this action by the Centers for Medicare & Medicaid Services in response to Plaintiff's subpoena and which Plaintiff subsequently produced to Defendant on July 15, 2021, and the burden of deriving or ascertaining the answer will be substantially the same for either party. Plaintiff objects to this interrogatory to the extent that Defendant is seeking to force Plaintiff to prematurely adopt or lock into a legal position.

Subject to the foregoing objections and general objections, Plaintiff responds as follows: A "claim" is "any request or demand ... for money or property" presented to an officer, employee, or agent of the United States. 31 U.S.C. § 3729(b)(2). Plaintiff alleges that all claims for payment for Remicade, Simponi ARIA, and related infusion procedures that health care providers associated with the Phase 1 Accounts submitted to Medicare on or after October 28, 2010 and after the Phase 1 Account received one or more of the services, presentations, or programs identified in Plaintiff's response to Interrogatory 2 constitute claims that were false or fraudulent in violation of 31 U.S.C. § 3729(a)(1)(A) & (B). The illegal remuneration that Defendant provided to the Phase 1 Accounts before and after October 28, 2010 induced and influenced the providers associated with the Phase 1 Accounts to prescribe and administer Remicade and/or Simponi ARIA infusions to Medicare beneficiaries and caused the providers to subsequently bill Medicare for the drugs and infusion services. There was a causal connection between the alleged Anti-Kickback Statute violations and the subsequent false claims for

reimbursement submitted to Medicare. The Medicare beneficiaries who were prescribed the Remicade or Simponi ARIA infusions by the health care providers associated with the Phase 1 Accounts after the accounts received the alleged illegal remuneration were exposed to an illegal referral, order, or purchase. Plaintiff alleges that the causation requirements for Anti-Kickback Statute violations under First Circuit and District of Massachusetts law are met. The specific billing information concerning false claims that health care providers associated with the Phase 1 Accounts submitted to Medicare between 1998 and May 15, 2021 are included in the Medicare claims data produced to Defendant on July 15, 2021.

**INTERROGATORY 13: State the basis for Your contention that the claims identified in Your response to Interrogatory No. 12 were False Claims.**

**RESPONSE TO INTERROGATORY 13:**

To the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute and False Claims Act violation, Plaintiff objects because it is misusing this interrogatory to improperly attempt to obtain a detailed narrative of Plaintiff's case or pretrial memorandum. Plaintiff objects on the ground that responding to this interrogatory would be unduly burdensome, and it is not proportional to Defendant's needs during the discovery stage. Defendant has failed to show why the information requested in this Interrogatory is appropriate or necessary at this early stage of the discovery process. Plaintiff also objects on the ground that the interrogatory is premature because discovery is ongoing and is only in the initial stages and Plaintiff has not yet completed her pretrial investigation, discovery, or preparation of her case for trial. Additionally, documents that support Plaintiff's claims are in the custody, possession, or control of Defendant and are still in the process of being produced and reviewed and numerous depositions still need to be taken. Plaintiff also objects to

this interrogatory to the extent that Defendant is seeking to force Plaintiff to prematurely adopt or lock into a legal position.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: *See* Plaintiff's response to Interrogatory 11. The claims identified in Plaintiff's response to Interrogatory 12 were false or fraudulent in violation of 31 U.S.C. § 3729(a)(1)(A) & (B) because:

- (a) The claims "include[d] items or services resulting from a violation of [the Anti-Kickback Statute] ..." 42 U.S.C. § 1320a-7b(g). And "an [Anti-Kickback Statute] violation that results in a federal health care payment is a per se false claim under the [False Claims Act]." *United States v. Regeneron Pharm. Inc.*, Civ. No. 20-11217-FDS, 2020 WL 7130004, at \*7 (D. Mass. Dec. 4, 2020) (quoting *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019)).
- (b) In the claim, the health care providers falsely represented to Medicare that they had not received illegal remuneration and that they had complied with the Anti-Kickback Statute in providing and billing for the Remicade, Simponi ARIA, and related infusions. The express representation providers made in bills submitted on Form CMS-1500 to Medicare regarding compliance with the Anti-Kickback Statute can be viewed at ¶ 28 of the Second Amended Complaint and CMS000005 – CMS000008.
- (c) The health care providers had falsely certified in their provider enrollment agreements with Medicare that they would comply with the Anti-Kickback Statute. The express representation providers made in enrollment agreements with Medicare regarding compliance with the Anti-Kickback Statute is publicly available and can also be viewed at ¶ 26 of the Second Amended Complaint. In submitting claims for payment for Remicade, Simponi ARIA, and related infusion services after receiving the services and related

presentations and programs identified in the response to Interrogatory 2, the providers falsely represented that they were complying with the certification made in their enrollment agreements.

Plaintiff will supplement this response and list the evidentiary support for the falsity element of her False Claims Act violation claims after substantial discovery has been completed.

**INTERROGATORY 14: State the basis for Your contention in Count I, as it relates to the Phase One Accounts, that Defendant “caused the health care providers to present claims for reimbursement to Medicare . . . that were false or fraudulent because the providers violated the Federal AKS and State AKS by accepting the kickbacks from Janssen.”**

**RESPONSE TO INTERROGATORY 14:**

To the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute violation and each corresponding False Claims Act violation involving the Phase 1 Accounts, Plaintiff objects because it is misusing this interrogatory to improperly attempt to obtain a detailed narrative of Plaintiff’s case or pretrial memorandum. Plaintiff objects on the ground that responding to this interrogatory would be unduly burdensome, and it is not proportional to Defendant’s needs during the discovery stage. Defendant has failed to show why the information requested in this Interrogatory is appropriate or necessary at this early stage of the discovery process. Plaintiff also objects on the ground that the interrogatory is premature because discovery is ongoing and is only in the initial stages. Additionally, documents that support Plaintiff’s claims are in the custody, possession, or control of Defendant and are still in the process of being produced and reviewed and numerous depositions still need to be taken.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: *See* Plaintiff's responses to Interrogatories 2, 5, 10, 11, 12, and 13. As a result of its knowing and willful offering and provision of the services and related presentations and programs identified in Plaintiff's response to Interrogatory 2 to induce health care providers associated with the Phase 1 Accounts to prescribe and infuse Remicade and Simponi ARIA to Medicare beneficiaries in violation of the Anti-Kickback Statute, Defendant caused the health care providers associated with the Phase 1 Accounts to present claims for reimbursement to Medicare that were false or fraudulent under 31 U.S.C. § 3729(a)(1)(A). The claims for reimbursement submitted by the health care providers associated with the Phase 1 Accounts were false claims under the False Claims Act because they included items and services (Remicade, Simponi ARIA, and/or related infusion procedures) resulting from violations of the Anti-Kickback Statute. *See* 42 U.S.C. § 1320a-7b(g); *United States v. Regeneron Pharm. Inc.*, Civ. No. 20-11217-FDS, 2020 WL 7130004, at \*7 (D. Mass. Dec. 4, 2020) ("an [Anti-Kickback Statute] violation that results in a federal health care payment is a per se false claim under the [False Claims Act].") (quoting *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019)). The claims for reimbursement submitted by the health care providers associated with the Phase 1 Accounts were also false claims under the False Claims Act because the health care providers falsely certified, stated, and/or represented in connection with each claim that they submitted to Medicare on or after October 28, 2010, in which they requested and received reimbursement for Remicade, Simponi ARIA, and/or related infusion services, that the claim complied with the Anti-Kickback Statute. In addition, Plaintiff directs Janssen to Plaintiff's Second Amended Complaint and Plaintiff's briefing in opposition to Janssen's motion to dismiss the Second Amended Complaint, and Plaintiff's initial disclosures. Plaintiff will update her initial



disclosures once Janssen has provided all the witness information that the Court ordered it to provide in the March 9, 2023 Memorandum and Order.

Plaintiff will supplement this response and list the evidentiary support for her 31 U.S.C. § 3729(a)(1)(A) violation claims after substantial discovery has been completed.

**INTERROGATORY 15: State the basis for Your contention in Count II, as it relates to the Phase One Accounts, that “Janssen caused health care providers to make false records or statements that were material to getting false or fraudulent claims paid by Medicare.”**

**RESPONSE TO INTERROGATORY 15:**

To the extent that this interrogatory is requesting that Plaintiff state the evidentiary support for each alleged Anti-Kickback Statute violation and each corresponding False Claims Act violation involving the Phase 1 Accounts, Plaintiff objects because it is misusing this interrogatory to attempt to improperly obtain a detailed narrative of Plaintiff’s case or pretrial memorandum. Plaintiff objects on the ground that responding to this interrogatory would be unduly burdensome, and it is not proportional to Defendant’s needs during the discovery stage. Defendant has failed to show why the information requested in this Interrogatory is appropriate or necessary at this early stage of the discovery process. Plaintiff also objects on the ground that the interrogatory is premature because discovery is ongoing and is only in the initial stages. Additionally, documents that support Plaintiff’s claims are in the custody, possession, or control of Defendant and are still in the process of being produced and reviewed and numerous depositions still need to be taken.

Subject to the foregoing objections and the general objections, Plaintiff responds as follows: *See* Plaintiff’s responses to Interrogatories 2, 5, 10, 11, 12, and 13. As a result of its knowing and willful offering and provision of the services and related presentations and

programs identified in Plaintiff's response to Interrogatory 2 to induce health care providers associated with the Phase 1 Accounts to prescribe and infuse Remicade or Simponi ARIA to Medicare beneficiaries in violation of the Anti-Kickback Statute, Defendant, in violation of 31 U.S.C. § 3729(a)(1)(B), caused health care providers to make false records or statements that were material to getting false or fraudulent claims paid by Medicare. More specifically, the health care providers associated with the Phase 1 Accounts falsely certified, stated, and/or represented in connection with each claim that they submitted to Medicare on or after October 28, 2010, in which they requested and received reimbursement for Remicade, Simponi ARIA, and/or related infusion services that the claim complied with the Anti-Kickback Statute. The health care providers associated with the Phase 1 Accounts also falsely represented that they were complying with the obligation under their provider enrollment agreements with Medicare that they were not accepting or receiving remuneration that violated the Anti-Kickback Statute.

In addition, Plaintiff directs Janssen to Plaintiff's Second Amended Complaint and Plaintiff's briefing in opposition to Janssen's motion to dismiss the Second Amended Complaint, and Plaintiff's initial disclosures. Plaintiff will update her initial disclosures once Janssen has provided all the witness information that the Court ordered it to provide in the March 9, 2023 Memorandum and Order.

Plaintiff will supplement this response and list the evidentiary support for her 31 U.S.C. § 3729(a)(1)(B) violation claims after substantial discovery has been completed.

**INTERROGATORY 16: State the basis for Your contention in Counts I and II that the United States was “unaware” that Janssen provided in-office infusion support services.**

**RESPONSE TO INTERROGATORY 16:**

Plaintiff objects to this interrogatory because the information it seeks is not relevant to any claim or defense asserted in this action.

Subject to the foregoing objections and general objections, Plaintiff responds as follows: In Counts I and Counts II, Plaintiff alleged that the United States was “unaware of the foregoing circumstances and conduct.” Plaintiff is not aware of evidence demonstrating that, before Plaintiff commenced this action, the United States was aware of the alleged circumstances and conduct underlying Counts I and II, including that Janssen knowingly and willfully regularly offered and provided the free services and related presentations and programs alleged in the Second Amended Complaint (directly and indirectly through outside consultants) to select physician practices to induce the physicians to purchase, order, and infuse Remicade and/or Simponi ARIA to patients including Medicare beneficiaries.

**INTERROGATORY 17: Identify any party or entity holding a contingency interest in the outcome of this case (excluding any arrangement with counsel).**

**RESPONSE TO INTERROGATORY 17:**

Plaintiff objects to the term “contingency interest” as vague and ambiguous. Plaintiff objects to this interrogatory because the information it seeks is not relevant to any claim or defense asserted in this action.

Subject to the foregoing objection and general objections, Plaintiff is the only relator in this action and correspondingly is the only person who can be awarded a portion of the proceeds of this action under 31 U.S.C. § 3730(d)(2). The only parties or entities that hold a “contingency

interest in the outcome of this case” are the United States and Plaintiff and her counsel. Plaintiff does not have an agreement with a litigation funder/litigation finance company.

**INTERROGATORY 18: Explain, in detail, all information that You provided to the Government, either in writing or orally, before filing this action.**

**RESPONSE TO INTERROGATORY 18:**

Plaintiff objects to this interrogatory on the grounds that it seeks information that is protected from discovery pursuant to the attorney-client privilege, attorney work product doctrine, common interest privilege, joint prosecution privilege, or any other applicable privilege, protection, immunity, or limitation on discovery. Plaintiff also objects to interrogatory to the extent that it seeks information that Plaintiff provided to the government that is not relevant to the subject matter of this action.

Subject to the foregoing objections and general objections, Plaintiff responds as follows: The only information that Plaintiff provided to the Federal Government concerning Defendant’s alleged violations of the Anti-Kickback Statute and the False Claims Act before filing this action was provided to the Department of Justice. All such information was provided on Plaintiff’s behalf by her counsel. Plaintiff’s counsel provided the Department of Justice the following written information concerning this action before October 28, 2016:

Oct. 11, 2016	Relator_Govt_Comms001003 (the reason the document is redacted is described on Nov. 1, 2021 privilege log at Index No. 88)
Oct. 19, 2016	Relator_Govt_Comms000615 (the reason the document is redacted is described on Nov. 1, 2021 privilege log at Index No. 45)
Oct. 19, 2016	Relator_Govt_Comms000629 (the reason the document is being withheld is described on Nov. 1, 2021 privilege log at Index No. 45.01)
Oct. 19, 2016	REL000001 - REL001598
Oct. 22, 2016	Relator_Govt_Comms001753 (the reason the document is redacted is described on Nov. 1, 2021 privilege log at Index No. 120)

In addition, Plaintiff's counsel, Casey Preston and Gary Azorsky, spoke by telephone to then Assistant U.S. Attorney Gregg Shapiro on October 14, 2016, concerning Plaintiff's allegations and claims asserted in this action. This was the only oral communication between Plaintiff's counsel and the Federal Government concerning Plaintiff's allegations and claims that occurred before the complaint was filed with the Court on October 28, 2016. The information shared during the October 14, 2016 telephone meeting was prepared in anticipation of litigation and/or trial and contained both the Department of Justice's and Plaintiff's counsel's mental impressions, conclusions, opinions, and/or legal theories. The Department of Justice and Plaintiff's counsel shared and reviewed this attorney work product with each other in confidence pursuant to the Common Interest Doctrine and the False Claims Act.

DATED: March 17, 2023

/s/ Casey M. Preston

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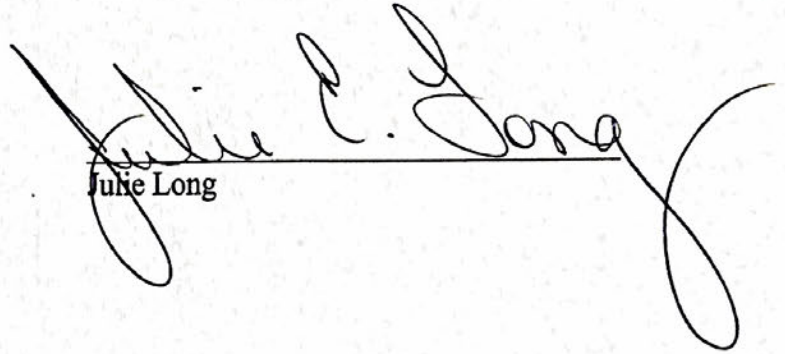
*Counsel for Plaintiff Relator Julie Long*

**VERIFICATION**

I am the plaintiff-relator in this action and have reviewed the foregoing supplemental responses to Defendant's Interrogatories 6 to 18.

I verify under penalty of perjury that the factual statements contained in the foregoing supplemental responses to Defendant's Interrogatories 6 to 18 are true and correct to the best of my knowledge, information, and belief.

Executed on March 17, 2023

  
Julie Long

**CERTIFICATE OF SERVICE**

I hereby certify that on March 17, 2023, a copy of the foregoing Plaintiff's Supplemental Objections and Responses to Defendant's Interrogatories 6 to 18 was served electronically on the following counsel:

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\_\_\_\_\_  
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